July 28, 2005

Barbara Buchner
Technical Contact
INDSPEC Chemical Corporation
1010 William Pitt Way
Pittsburg, PA 15238

Dear Ms. Buchner:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Resorcinol posted on the ChemRTK HPV Challenge Program Web site on July 7, 2004. I commend INDSPEC Chemical Corporation for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

The test plan indicated that, prior to submission of resorcinol information under the HPV Challenge Program, a 2-generation reproductive toxicity study in rats was already in progress. If the testing was in response to the HPV Challenge Program, according to HPV Challenge Program guidance, INDSPEC should have waited until the close of the public comment period before initiating any needed testing.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that INDSPEC advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Mark Townsend, Acting Chief of the HPV Chemicals Branch, at 202-564-8617. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: M. E. Weber
J. Willis

EPA Comments on Chemical RTK HPV Challenge Submission:
Resorcinol

Summary of EPA Comments

The sponsor, INDSPEC Chemical Corporation, submitted a test plan and robust summaries to EPA for 1,3-Benzenediol (Resorcinol, CAS No. 108-46-3) dated June 15, 2004. EPA posted the submission on the ChemRTK HPV Challenge Website on July 7, 2004.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties. The submitted data are adequate for the purposes of the HPV Challenge Program. The submitter needs to correct its estimated vapor pressure and water solubility values.

2. Environmental Fate. The submitter needs to provide Level III fugacity data and experimental details for the critical biodegradation study. The submitter needs to address deficiencies in the robust summaries.

3. Health Effects. EPA reserves judgement on the data submitted for acute, repeated-dose, genetic, and developmental toxicity endpoints pending submission of the adequately revised robust summaries.

4. Ecological Effects. EPA reserves judgement on all ecological endpoints until the submitter provides critical missing data elements for all key studies in the robust summaries.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

EPA Comments on the 1,3-benzenediol (Resorcinol) Challenge Submission

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, partition coefficient and water solubility)

The data provided by the submitter for these endpoints are adequate for the purposes of the HPV Challenge Program. The submitter needs to correct the following errors:

Vapor pressure. The estimated vapor pressure of 0.011 mm Hg equals 0.01466 hPa, not 0.1463 hPa as reported in the robust summary.

Water solubility. In test plan Table 2 (page 7) the measured water solubility value from the Merck Index should be 1.11×10^6 mg/L, and the estimated value should be 8.571×10^4 **mg**/L.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The data provided by the submitter for photodegradation, stability in water, and biodegradation are adequate for the purposes of the HPV Challenge Program. The submitter needs to provide biodegradation experimental details in the robust summary.

Fugacity. The submitter provided fugacity data using level I modeling. Although EPA had previously recommended the use of EQC Level I, EPA now recommends the use of the EQC level III model, which provides values that are more realistic and useful for estimating a chemical's fate in the environment.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Data were submitted for acute, repeated-dose, genetic, and developmental toxicity endpoints. However, the robust summaries are not detailed enough to assess their adequacy. Therefore, EPA reserves judgement on data adequacy pending submission of revised robust summaries.

Reproductive toxicity. No data were submitted. The test plan indicated that a 2-generation reproductive toxicity study in rats is in progress. Data from the evaluation of reproductive organs from an adequate 90-day repeated-dose toxicity study and an adequate developmental toxicity study can also be used to address this endpoint for the purposes of the HPV Challenge Program.

Ecological Effects (fish, invertebrates, and algae)

EPA reserves judgement on all three ecotoxicity endpoints pending submission of critical missing data elements for the key study robust summaries.

Specific Comments on the Robust Summaries

General

The robust summaries did not provide enough detail. The submitter should consult EPA guidance documents for the preparation of robust summaries (http://www.epa.gov/opptintr/chemrtk/guidocs.htm).

Environmental Fate

Biodegradation. The submitter needs to provide details such as test conditions and test substance purity.

Health Effects

Acute Toxicity. Missing study details include information on test substance composition/purity, duration of post-exposure observation period, statistical methods, and method of test substance administration.

Repeated-Dose Toxicity. The missing study details include hematology and clinical chemistry parameters, number of animals per dose, statistical methods, and whether or not full set of organs was weighed and tissues were examined histopathologically.

Genetic Toxicity (Gene Mutations). Missing study details include information on test substance purity/composition, mean number of revertant colonies per plate, culture conditions, positive/negative controls used/responses, statistical methods, evidence of testing to cytotoxic concentrations, and criteria for a positive response.

Genetic Toxicity (Chromosomal Aberrations). Missing study details include information on test substance composition/purity, number of replicates per concentration, positive/negative control use/response, signs of toxicity per concentration, statistical methods, and incubation conditions.

Developmental Toxicity. Missing study details include evidence that the highest tested dose was maternally toxic, test substance purity/composition, specific method of test substance administration, date of study, statistical methods, proportion of fetuses evaluated for external visceral and skeletal

malformations, changes in maternal body weight, fetal body weight, control use/response, hematological and clinical biochemical parameters examined, and specific tissues subjected to histopathological examination.

Ecological Effects

Fish. Missing study details include test substance composition/purity, tested concentrations, number of fish per concentration, loading rate of fish, control use/response, statistical methods used, mortality and/or effects at each concentration, and water chemistry measurements such as pH and hardness throughout the test.

Invertebrates. Study details that are missing from the summaries included number of daphnids tested per concentration, loading rate of daphnids, age of daphnids, oxygen saturation of water, control use/response, mortality and/or effects at each dose, and water chemistry measurements (i.e., water hardness, pH, dissolved oxygen, and temperature) throughout the test.

Algae. The following study details are missing in the summary: control use/response, statistical methods, effects at different concentrations, cell concentration information, and water chemistry measurements (i.e., water hardness, pH, dissolved oxygen, and temperature) throughout the test.

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.